Prevalence of cardiovascular disease and their risk factors in patients with ankylosing spondylitis.

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This research must answer the following questions: (1) what is the prevalence of CVD in AS patients?(2) what is the incidence of CVD in patients with AS? (3) which risk factors contribute to the development of CVD in AS? (4) to which extent AS...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON30425

Source
ToetsingOnline

Brief title
CarAS: Cardiovascular disease in Ankylosing Spondylitis

Condition

- Cardiac disorders, signs and symptoms NEC
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
CVD cardiovascular disease

Research involving
Human

Sponsors and support

Primary sponsor: Jan van Breemen Instituut
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ankylosing spondylitis (AS), cardiovascular disease (CVD), incidence, prevalence

Outcome measures

Primary outcome

CVD will be defined as an objectified history of coronary, cerebral or peripheral arterial disease. Coronary diseases will be defined as having a history of myocardial infarction, surgery for ischemic heart disease. Cerebrovascular disease is defined as a history of a transient ischemic attack, a stroke, or a carotid endarterectomy. Peripheral arterial disease will be defined as an aneurysm of the aorta abdominalis, peripheral arterial reconstructive surgery, limb amputation.

Secondary outcome

Demographic data: age, gender, disease duration, disease onset, co-morbidity, radiographic damage, medical history, medication history, family history.

AS disease activity: Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Metrology Index (BASMI), Maastricht Ankylosing Spondylitis Enthesis Score (MASES), Ankylosing Spondylitis (Asqol) scores, history of orthopedic surgery, (history of) extra-articular manifestations.

Cardiovascular risk factors: smoking, family history of premature CVD, (history of) hypertension, (history of) dyslipidemia, (history of) thyroid gland failure, and diabetes mellitus.

Physical examination: blood pressure, pulse, height, length, body mass index (BMI), waist circumference, hip circumference, waist hip ratio (WHI), ankle branchial pressure index, EKG.

Laboratory: Erythrocyte sedimentation rate (ESR), C-reactive protein, glucose (fasting), HbA1c, platelet counts, creatinine, thyroid stimulating hormone (TSH), lipids (total cholesterol, HDL, TG, Apo-A, Apo-B).

Study description

Background summary

A limited number of studies indicate that (cardiovascular) mortality and morbidity among patients with AS might be increased when compared with age- and sex matched controls. Studies investigating mortality in AS show elevated standardized mortality ratios (SMR*s) of approximately 1.6-1.9. Cardiovascular disease (CVD) seems to be the major cause of this excessive mortality [1-5]. This postulated increased cardiovascular risk can only partially be explained by an increased prevalence of traditional cardiovascular risk factors and/or characteristic cardiac manifestations such as aortic insufficiency and diastolic dysfunction [6,7]. Altogether, the precise magnitude of the postulated increased cardiovascular risk in AS is not known.

Other inflammatory rheumatic diseases, such as rheumatoid arthritis (RA), are already known to be associated with an increased cardiovascular risk in comparison with the general population [8]. Data regarding cardiovascular risk factors among patients with AS are limited and there are no data about the relationship between inflammation and cardiovascular diseases in AS. This postulated enhanced cardiovascular risk in AS could be caused by:

1. A higher prevalence of conventional cardiovascular risk factors in SpA, such as smoking, atherogenic lipid profile, hypertension, diabetes mellitus, a high body mass index, high levels of homocysteine, high levels of fibrinogen, increased platelets, and hypercoagulability;

2. SpA is a risk factor for developing cardiovascular diseases, eg, due to:
a. Decreased physical activity;
b. Inflammation.

3. Undertreatment of cardiovascular comorbidity, eg, hypertension.

Alterations in the frequency of cardiovascular risk factors such as smoking, abnormal lipid profile, hypertension, increased fibrinogen level, enhanced number of platelets, and hypercoagulability may contribute to the higher cardiovascular risk in patients with AS. In addition, deterioration of physical function, and inflammation may also contribute to cardiovascular risk. Chronic inflammation may act independently or synergistically with other cardiovascular risk factors in the pathogenesis of atherosclerosis [9]. Recent research has shown that systemic inflammation plays a pivotal role in the development of atherosclerosis [10,11]. Immune cells dominate early atherosclerotic lesions, their effector molecules accelerate progression of the lesions and inflammation elicits CVD. Hence, inflammation is thought to be the key risk factor explaining the increased cardiovascular risk in patients with AS. The finding that the increased mortality is dependent upon disease severity supports this idea [12]. Finally, we should be aware of the potential existence of underrecognition and undertreatment of cardiovascular morbidity, which may lead to higher cardiovascular risk [13].

Until now, data regarding the cardiovascular risk profile in patients with AS are limited and inconclusive. There is accumulating evidence for a higher prevalence of CVD due to atherosclerosis, but studies investigating this topic are lacking.

Study objective

This research must answer the following questions:

(1) what is the prevalence of CVD in AS patients?
(2) what is the incidence of CVD in patients with AS?
(3) which risk factors contribute to the development of CVD in AS?
(4) to which extent AS influences the cardiovascular risk?

Study design

A multi-centre cohort study with a nested case control design. A cardiovascular questionnaire will be sent to all registered AS patients aged 50-75 years in the Jan van Breemen Clinics as well as in the VU university medical centre. Each respondent with a history of CVD will be invited at the Jan van Breemen Clinics and an equal age and sex matched AS patient will be added and they will be invited at the Jan van Breemen Clinics also. This procedure will be repeated yearly and included patients will be followed for at least 5 years.

Study burden and risks

Risk: none

Benefit: Cardiovascular disease (CVD) seems to be the major cause of the excess morbidity and mortality in patients with AS, which is partly due to atherosclerosis. Inflammation is thought to play a pivotal role in the development of atherosclerosis. As in other autoimmune diseases it is important to explore the cardiovascular burden in AS as well as potential targets for intervention to lower this risk and decrease mortality due to AS.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Patients with AS (according to the modified New York criteria);
- aged 50 years and older;
- registered at the Jan van Breemen Institute and/or the VU university medical center.

Exclusion criteria

none

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	350
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL15378.048.07